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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/505,898	02/17/2000	Kirti Dave	065733/2262	7146

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EXAMINER	
WINKLER, ULRIKE	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/505,898	DAVE ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-54 and 56-115* is/are pending in the application.

4a) Of the above claim(s) *48-53,57-59,66-71,82-87,93-105 and 108-115* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *44-47,54,56,60-65,72-92,106 and 107* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed June 10, 2005 in response to the Office action of December 10, 2004 is acknowledged and has been entered. Claims 106-115 have been added. Claims 44-47, 54-56, 60-65, 72-81, 88-92 and newly added claims 106 and 107 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Newly submitted claim 108-115 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 108-115 are drawn to a device which is separate and distinct from the methods now under consideration.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 108-115 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The rejection of claims 44-46, 54, 56, 60-65, 72-81, 88-92 and newly added claims 106 and 107 under 35 U.S.C. 103(a) over Oprandy et al. (Journal of Clinical Microbiology, 1990, see IDS #5), Huang et al. (U.S.Pat. No. 5,712,172), WHO Bulletin (Bulletin of the World Health Organization, 1996, see IDS #5), Snowden et al. (Journal of Immunological Methods, 1991, see IDS #5), Pawlak et al. (U.S. Pat. No. 5,770,460) and Hildreth eta l. (Journal of Clinical Microbiology, 1982) **is maintained for reasons of record.**

Applicant's arguments and the Office's response are essentially the same as those of record. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicants arguments and the Offices response are essentially the same of record. Applicants' arguments are that none of the references are anticipatory. Applicants argue that the present invention has a wide application and makes use of a format that is more applicable to commercial production for field-collected samples.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this instant applicants are claiming a method of detecting an analyte. The analyte detection depends on the specific interaction between the antibody and the analyte. The art recognizes that it is the antibody/analyte interaction that provides the means for the actual detecting property. The art also recognizes that regardless of the format of the assay that is used it is still only dependent on the antibody/analyte interaction.

The instant invention is drawn to a method of analyzing an arthropod sample for an agent that may cause disease in mammals.

The method (claim 44) comprising the following steps:

(a) obtaining the arthropod sample,

(b) treating the sample with buffered saline and a non-ionic detergent to expose at least one analyte from the arthropod,

(c) contacting the liquid permeable support which contains a capture reagent with the sample from the previous step

(d) allowing liquid to flow through the support by capillary action,

(e) detecting the presence of the analyte and

(f) using a plurality of detectable analyte specific reagents for detecting arthropod carried agents.

The dependent claims contain the following additional limitations: the detection moiety, the placement of the analyte specific reagent, the arthropod is a mosquito, the liquid permeable support contains a control area, the analyte specific reagents are monoclonal antibodies, or gold and latex labeled antibodies.

Applicants arguments are regarding point (b)/(c) of the method steps. Applicants' arguments are that the prior art samples always contain an additional step to clarify the arthropod sample before applying the method steps. The independent claims 44, 63 and 79 all utilize the transitional term comprising. MPEP 2111.03 The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other

elements may be added and still form a construct within the scope of the claim.) In this instance the additional clarification step taught in the prior art would fall within the meaning of the claim. Even if the claim limitation were to exclude a clarification step the use of non-purified samples is contemplated in the prior art. "The sample receiving zone may further serve to remove debris or interfering substances from the sample by physical entrapment without impeding the non-bibulous lateral flow (see U.S. Pat # 5,770,460 column 2, lines 55-59).

The significance of the teaching of each of the prior references are as follows:

Oprandy et al. teaches using a mosquito for the purpose of detecting a malarial antigen when absorbed onto a solid membrane. Thus at the time the invention was made the ordinary artisan was aware that mosquito could be tested for the presence of malarial antigen in the insect vector itself. The detection was dependent on the antibody antigen interaction. The reference established that a mosquito could be tested for the presence of an agent that causes disease in a mammal. The reference is applicable because some of the dependent claims specifically look to detecting malarial antigen in the mosquito.

Hildreth et al. teach the public health surveillance of arboviruses typically involve, detecting human infection and infection in the mosquito vector population itself. The risk for human infection increases with the increase in the number of mosquitoes carrying the virus. Mosquitoes were ground up in saline supplemented with fetal bovine serum (a polypeptide component), penicillin (an antimicrobial component) and streptomycin (an antimicrobial component) (see page 880, column 1, 2nd paragraph). The mosquito pools are diluted in a buffer containing 0.1% Tween 20, in saline with heat inactivated serum before adding to the Elisa plate. Thus the antibody/analyte interaction occurs in the presence of non-ionic detergent. The

effectiveness of the procedure is dependent on the antibody/analyte interaction. The reference teaches that at the time the invention was made the ordinary artisan was aware that adding inhibitors and adding a polypeptide component adds to the stability of the sample to be tested.

Snowden et al. teaches a dipstick assay that combines the concepts of a double antibody sandwich ELISA, dot blotting and colloidal particle linked antibodies to produce a dipstick for multiple antigen detection. Without the antibody/analyte interaction the dipstick would not function. The dipstick used antibodies that were known to interact with an antigen. The reference teaches that known antigen/analyte interactions can be easily transformed into different assay formats without losing the critical antibody analyte interaction, which is necessary for the detection. Here capture antibodies where linked to the dipstick (made up of nitrocellulose membrane). After attaching the capture reagent the remaining binding sites were blocked. The dipstick was then placed an analyte containing liquid. After the interaction with the analyte the dipstick is placed into an analyte detecting reagent made up of an antibody linked to a dye. The dipstick is then analyzed for color development. The reference has immediate applicability to identify insect blood meals. The reference provides the motivation that the same technique can be applied for qualitative antigen (analyte) detection test for mammal diseases carried by the mosquito (see page 58, column 1, last paragraph).

WHO reference teaches that a dipstick assay can be used to detect malarial analyte in a blood sample from patient. The steps involved in the WHO reference are similar to the method taught by Snowden et al. above. Here there is a dipstick with a capture antibody, which is exposed to a liquid containing an analyte, the dipstick is incubated with detecting agent an analyzed for a positive reaction. The assay is dependence on the antibody/antigen interaction.

The ordinary artisan is aware that the malarial parasite has different epitopes (analyte) exposed during different life stages of the parasite. Thus to assay a mosquito for the presence of a malarial antigen would require the use of an antibody that recognizes a mosquito stage analyte of malaria, such as the one taught by Oprandy et al.

Huang et al. teaches a lateral flow device comprising a sample receiving area, an analyte detection area made up of mobile labeling areas followed by a capture reagent area. The analyte detection area sits between the sample receiving area and the end flow region. The method of detection using the device depends on the antibody/analyte interaction of interest and can be modified accordingly (see column 1, lines 45-49).

Pawlak et al. teaches a similar later flow device to that of Huang et al. above. The device comprises a sample receiving zone, a labeling zone, a capture zone and an absorbent end zone. The reference teaches that the sample receiving zone can serve to remove debris or interfering substance by physical entrapment without impeding nonbibulous lateral flow. Thus the reference teaches that the sample may contain debris and the sample does not need to be clarified before using device. The method of detection using the device depends on the antibody/analyte interaction of interest and can be modified accordingly.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the analyte detection reagents as taught by Oprandy et al. and/or Hildreth et al. and apply them to the device taught by Huang et al., Pawlak et al., the WHO bulletin and Snowden et al. One having ordinary skill in the art would recognize that the methods of detection using the various devices are dependent on the antibody/analyte interaction and are not dependent the particulars of the device to carry out the detection step.

One having ordinary skill in the art would have been motivated to move from an ELISA based assay system or a Western blotting system of a dipstick or lateral flow device in order to determine the risk of arthropod-vector disease spread it is necessary to survey the insect population for these etiologic agent (as taught by Hildreth et al.). This information is important to assess the efficacy of insect control and abatement programs.

One having ordinary skill in the art would have a high expectation of success in applying the antibodies and the methods of exposing the analyte using detergents as taught by Oprandy et al. and/or Hildreth et al. and formulate them into the device as taught by Huang et al., the WHO Bulletin and Snowden et al. Snowden et al. clearly teaches that reagents used for an ELISA based test are predictably adaptable to the dipstick protocol. In the experiments comparing blood meal analysis of mosquito using the dipstick assay and ELISA showed 100% agreement and 100% accuracy (see Snowden et al., page 58, last paragraph). Therefore, the instant invention is obvious over the cited references.

The rejection of claims 44-47, 54, 56, 60-65, 72-81, 88-92 and newly added claims 106 and 107 under 35 U.S.C. 103(a) as being unpatentable over Oprandy et al. (Journal of Clinical Microbiology, 1990, from applicant's IDS), Huang et al. (U.S.Pat. No. 5,712,172), WHO Bulletin (Bulletin of the World Health Organization, 1996, see IDS #5) and Snowden et al. (Journal of Immunological Methods, 1991, see IDS #5), Pawlak et al. (U.S. Pat. No. 5,770,460) and Hildreth eta l. (Journal of Clinical Microbiology, 1982) in view of Rattanarithikuln et al. (American Journal of Tropical Medicine, 1996, from applicant's IDS) and Sithiprasasna et al.

(Annals of Tropical Medicine and Parasitology, from applicant's IDS) **is maintained** for reason of record.

Applicant's arguments and the Office's response are essentially the same as those set out in the above rejection. Applicant further argues that neither Rattanarithikuln et al. or Sithiprasasna et al. teach or motivate the selection of monoclonal antibodies for the detection of arthropod-borne disease vectors. This is not found convincing because Rattanarithikuln et al. teach using monoclonal antibodies in ELISA detection assay (see page 116, 3rd paragraph). Sithiprasasna et al. teach using monoclonal antibodies for the detection of Dengue virus a flavivirus (see page 399, column 1). The panel assay does not provide a contribution over the prior art. It is obvious from the prior art that Rattanarithikuln et al. disclosed that they used two different monoclonal antibodies in an ELISA assay to differentiate whether the misquotes carries *P. vivax* or *P. falciparum*. Merely changing the format of an assay (vertical v. horizontal or PVDF v nitrocellulose) that depends on the same unique interaction between an antibody and the analyte for its functions does not distinguish the instant invention over the prior art. Snowden et al. clearly teaches that reagents used for an ELISA based test are predictably adaptable to the dipstick protocol. In the experiments comparing blood meal analysis of mosquito using the dipstick assay and ELISA showed 100% agreement and 100% accuracy (see Snowden et al., page 58, last paragraph). Snowden et al. also teaches that the dipstick assay has the advantage that two or more antigens may be tested at the same time, indicating the efficiency of the assay method. Therefore, the instant invention is obvious over the prior art.

Conclusion

No claims allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Pat. No. 6,924,153.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

The official fax phone number for the organization where this application or proceeding is assigned is 703-872-9306; for informal communications please the fax phone number will change to 571-273-0912

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER 8/22/05